

REMARKS

Applicants submit the following suggested requirement for restriction (SRR) under 37 CFR 1.142(c), as set forth in 72 Fed. Reg. 46716, 46842 (August 21, 2007), in expectation of the same or similar rule coming into force at some time during the prosecution of this application.

This SRR is timely, as it is filed prior to a first official action on the merits or a requirement for restriction issued by the examiner. 37 CFR 1.142(c).

I. Summary of the Amendments to the Claims

Claims 84, 87, and 126 have been amended for clarity.

II. Identification and Election of Inventions

The applicants suggest restriction between the following three groups of inventions:

Group I: claims 84-88 (directed to a method of producing a comminuted sterile suspension of particles and to a sterile suspension prepared according to the method);

Group II: claims 89-122 (directed to a sterilizable particle size reduction apparatus for performing the method of Group I); and,

Group III: claims 123-141 (directed to a method of sterilizing the particle size reduction apparatus of Group II).

The applicants elect **Group I** (claims 84-88), without traverse. By this election, there are five total claims and two independent claims (claims 84 and 88). 37 CFR 1.75(b)(2), as set forth in 72 Fed. Reg. at 46836.

III. Propriety of Restriction

Restriction may be proper where inventions are related as disclosed but are distinct as claimed. MPEP § 806.

Groups I and III are related methods, as both relate to the same apparatus. Related process inventions are distinct if: (A) the inventions as claimed do not overlap in scope; (B) the inventions as claimed are not obvious variants; and, (C) the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect. MPEP § 806.05(j).

Thus, Groups I and III are distinct because: (A) Groups I and III have no overlapping subject matter, (B) the applicants submit that the inventions defined by Groups I and III are not obvious variants of each other, and (C) the methods of Groups I and III have materially different effects (i.e., the Group I claims form a comminuted sterile suspension of particles, while the Group III claims sterilize a particle size reduction apparatus). Accordingly, restriction between Groups I and III may be proper.

Groups I and II are related, as Group II is an apparatus for practicing the method of Group I. Groups II and III are related, as Group II is an apparatus for use in the method of Group III. A method and an apparatus for its practice are distinct if either of the following is true: (A) the method as claimed can be practiced by another materially different apparatus or by hand; or (B) the apparatus as claimed can be used to practice another materially different method. MPEP § 806.05(e).

Because the apparatus of Group II can be used in either of the methods of Group I or Group III (i.e., two methods with materially different effects; see above), Group II is distinct from both Group I and Group III. Accordingly, restriction as between Groups I/II and Groups II/III may be proper.

In view of the above remarks, the applicants submit that SRR is proper, and solicit an acknowledgement to that effect in the first official action on the merits.

Dated: _____

11/14/07

Respectfully submitted,

By _____

James P. Zeller

Registration No.: 28,491

MARSHALL, GERSTEIN & BORUN LLP

233 S. Wacker Drive, Suite 6300

Sears Tower

Chicago, Illinois 60606-6357

(312) 474-6300

Attorney for Applicant